BIOMET
MANUFACTURING CORP.

510(k) Summary

Preparation Date: March 6, 2013

AUG 3 0 2013

Applicant/Sponsor:
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587
Establishment Registration Number: 1825034

Contact Person:
Becky Earl
Regulatory Specialist

Proprietary Name: Sirius Femoral Stem

Common Name: Cemented modular hip prosthesis

Classification Name:

JDI— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350).

LZO—Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353).

KWZ— Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310).

MEH—Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353).

LPH—Hip joint metal/polymer/metal semi-constrained porous-coated, uncemented prosthesis (21 CFR 888.3358).

KWY—Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390).

JDG—Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360).

LZY—Hip joint (hemi-hip) acetabular metal cemented prosthesis (21 CFR 888.3370).

OQG—Prosthesis, hip, semi-constrained, metal/polymer + additive, porous uncemented (888.3358)

OQH—Hip, semi-constrained, cemented, metal/polymer + additive, cemented (21 CFR 888.3350)

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56 E. Bell Drive
Warsaw, IN 46582

OQI—Hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented (21 CFR 888.3353)

PBI—Prosthesis, hip, constrained, cemented or uncemented, metal/polymer, + additive (21 CFR 888.3310)

KWL—Hip Joint Femoral (Hemi-Hip) Metallic Cemented or Uncemented Prosthesis (21 CFR 888.3360)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Generation 4 (Gen 4) Polished Femoral Hip System with Proximal Cement Spacer — Biomet—(K052639)

Collarless Polished Taper (CPT) Stem —Zimmer—(K960658)

Device Description:

The Sirius femoral stem is a highly polished, double-tapered, cemented stem designed to reduce hip pain for patients and restore joint biomechanics and stability. The short stem is designed to fit a broad range of patient anatomies for primary or revision cases. The features include a collarless, highly polished, double-taper design, with a rectangular proximal geometry. The distal portion of the stem has a progressive diminishing cross-section. Each stem is packed with a winged and wingless centralizer, made of polymethylmethacrylate (PMMA), designed to help create a uniform mantle.. The size ranges are within the ranges of legally marketed predicates. The Sirius stem is made from Co-Cr-Mo, ASTM F799.

Intended Use:

Components are intended for cemented use and may be used in partial and total hip arthroplasties.

Indications for Use:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5. Revision procedures where other treatment or devices have failed.

The Sirius Femoral Hip Stem is intended for cemented use only and may be used in partial and total hip arthroplasties.

Summary of Technologies:

The technological characteristics are the same as the predicates identified in the Legally Marketed Devices to which substantial equivalence is claimed. The design is based on the taper-slip principle: the taper subsides at the stem/cement interface, and the double-taper becomes solidly engaged in the cement mantle. The geometry favors rotational stability to help minimize loosening. The stem is made of Co-Cr-Mo, ASTM F799, as are the predicates, and the centralizers are made of polymethylmethacrylate (PMMA). The Sirius stem is available in seven body sizes with numerous offsets to enable proper sizing and the Type 1 taper enables the choice of numerous modular heads. The Sirius stem features a short length, but the shortest stem in the Sirius system fits within the predicate range of sizes.

Non-Clinical Testing:

Nonclinical performance testing was performed to support substantial equivalence. The testing included Distal and Proximal Stem fatigue testing of the worst-case stem, consistent with the "Guidance for Industry and FDA Staff Non-clinical Information for Femoral Stem Prostheses", ISO 7206-4:2010, ASTM F2068-09 and ISO 7206-6:1992, Cobalt Chrome Modular Head Pull-off from a Type 1 Reduced Taper, as outlined in ISO 7206-10:2003, as well as a Range of Motion analysis consistent with ISO 21535:2009 and a Comparison/ Justification for Modular Connections, Fretting and Corrosion Testing.

Clinical Testing:

None provided as a basis for substantial equivalence.

The results of non-clinical testing demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 30, 2013

Ms. Becky Earl
Regulatory Specialist
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581

Re: K130610
Trade/Device Name: Sirius Femoral Hip Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, LZO, KWZ, MEH, LPH, KWY, JDG, LZY, OQG, OQH, OQI, PBI, KWL
Dated: May 31, 2013
Received: June 5, 2013

Dear Ms. Earl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130610

Device Name: Sirius Femoral Hip Stem

Indications For Use:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5. Revision procedures where other treatment or devices have failed.

The Sirius Femoral Hip Stem is intended for cemented use only and may be used in partial and total hip arthroplasties.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices